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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO.	:	09/600,564
APPLICANT	:	Florian KERN
FILED	:	001602us/JH/ml
EXAMINER	:	K.S. Shahnan Shah
ART UNIT	:	1645
FOR	:	METHOD FOR IDENTIFYING T-CELL STIMULATING PROTEIN FRAGMENTS

Hon. Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Consider 1
10/2/05
RE

September 15, 2004

DECLARATION PURSUANT TO 37 CFR § 1.132

Sir:

I, Florian Kern, of Berlin, Germany, am a research group leader at the Institute for Medical Immunology, at Charité – Universitätsmedizin Berlin, a well-known research institution. My vitae is shown in Exhibit I. My group works in the field of antigen specific T lymphocytes and has been involved in the development of assays based on short term stimulation of T lymphocytes with specific antigens, including short peptides derived from the amino acid sequence of pathogens including viruses. I am the principal author or senior-author of more than 15 Medline-indexed research articles in this field summarized in Exhibit II. I have carefully studied the article entitled *CD30 Induction and Cytokine Profiles in Hepatitis C Virus Core-Specific Peripheral Blood T Lymphocytes* that was published by R. Woitas et al. in the Journal of Immunology (1997) vol. 159: 1012-1018.

The above-named article describes methods used to identify peptides from Hepatitis-C Virus (HCV) core protein that stimulate T lymphocytes. When stimulated, T lymphocytes demonstrate increased cellular levels of marker proteins; e.g., the surface protein CD30, interferon-γ and one or more interleukins (e.g., IL-2, IL-4 and IL-10). The increase in

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September 15, 2004

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Consider 10/2/05 KS

Sir:

I, Holden T. Maecker, of Palo Alto, California, USA, am a Group manager at BD Biosciences in San Jose, Ca., USA, a company who is involved in the development and marketing of antigen-specific flow-cytometric assays. My vitae is shown in Exhibit I. My group is in charge of developing assays specifically concerning the detection of antigen specific T-cells using short term stimulation with specific antigens, including short peptides derived from the amino acid sequence of viral proteins. I am the principal author or senior-author of more than 20 Medline-indexed research articles in this field summarized in Exhibit II. I have carefully studied the article entitled *CD30 Induction and Cytokine Profiles in Hepatitis C Virus Core-Specific Peripheral Blood T Lymphocytes* that was published by R. Woitas et al. in the Journal of Immunology (1997) vol. 159: 1012-1018.

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Re.: Statement regarding the patent application of Dr. Florian Kern - METHOD FOR IDENTIFYING T-CELL STIMULATING PROTEIN FRAGMENTS, serial No 09/600,564

November 2, 2004

Sir:

I, Rainer P. Woitas, of Bonn, Germany, am a principal investigator and author of the article entitled *CD30 Induction and Cytokine Profiles in Hepatitis C Virus Core-Specific Peripheral Blood T Lymphocytes* that was published in the Journal of Immunology (1997) vol. 159: 1012-1018. Since that time, I have been an author of several research articles and reviews related to cellular immunity.

II, The above-named article describes methods used to identify antigen-specific T cell cytokine profiles induced by peptides from Hepatitis-C Virus (HCV) core protein. When stimulated, T lymphocytes demonstrate increased cellular levels of marker proteins; e.g., the surface protein CD30, interferon-γ and one or more interleukins (e.g., IL-2, IL-4 and IL-10). The increase in marker proteins was quantified by measuring the levels of CD30, interferon-γ and/or various interleukins in comparison to unstimulated T lymphocytes.

1. The method described in the article comprises contacting T lymphocytes with one or more short peptides corresponding to distinct regions of the HCV protein. Peptide-stimulated T lymphocytes were analyzed after immunolabeling of the T lymphocytes with fluorescent antibodies to form fluorescent immune complexes for each protein of interest. The basis of the assay is that the magnitude of the fluorescent signal measured by flow cytometry is proportional to the amount of fluorescent antibody-protein complex present, which in turn, reflects the amount of the protein being measured.

Considered 10/2/05 FZ